Case: 1:17-md-02804-DAP Doc #: 2802-2 Filed: 10/14/19 1 of 6. PageID #: 423751

### EXHIBIT 1



The past two decades have been characterized by increasing abuse and diversion of prescription drugs, including opioid medications, in the United States. The death toll from overdoses of prescription painkillers has more than tripled in the past decade. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every four hours for one month.

### The Opioid Crisis:

### Facts:

- It is estimated that more than 55,000 Americans die each year from a drug overdose, which has become the leading cause of death of individuals under the age of 50. Sixty percent of these deaths are caused by opioids. The jump in fatalities over the past 15 years has been staggering, a more than three-times increase.
- The opioid epidemic has cost the U.S. more than a trillion dollars since 2001, according to a recent Altrium study, and may exceed another \$500 billion over the next three years.

### The Wholesale Drug Distributors:

### Facts:

- Cardinal Health, AmerisourceBergen and McKesson Corp. are the nation's three biggest pharmaceutical distributors, responsible for shipping nearly 85 percent of all prescription drugs in the United States. Together they have combined annual revenues of \$400 billion and profits in the billions of dollars.
- Wholesale distributors have a duty under the federal Controlled Substances Act to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency.
- Distributors that supply controlled substances to pharmacies must design and operate a system to flag suspicious orders of controlled substances and in turn disclose those suspicious orders to state and federal authorities. The system is intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market.

### **Breach of Legal Duty:**

### Facts:

- Unintentionally released DEA ARCOS reports for the State of West Virginia demonstrate the extent to which the Wholesale Drug Distributors failed to uphold their legal duty to monitor and report suspicious orders and turned a blind eye as hundreds of millions of opioids flowed into communities across America.
- While nationwide ARCOS data has not been made available to the public, the West Virginia reports show that between 2007 and 2012, drug wholesalers shipped over 780 million doses of opiate painkillers to West Virginia, which has a population of 1.8 million. In one example, data demonstrates that wholesalers shipped nearly 21 million doses of painkillers to two pharmacies just blocks apart from each other in Williamson, WV, a town of 3,191.

### THE WHOLESALE DRUG DISTRIBUTORS vs. THE FACTS

**Distributor claim:** "Distributors regularly report suspicious activity and when appropriate – cut off the supply of product to customers when "red flags" of possible drug diversion or other illegal activity are observed. Distributors report controlled substance orders that are filled and those that are deemed suspicious to the DEA, and have robust controls in place to monitor distribution."

Fact: According to the ARCOS data, more that 6.5 million prescription opiates were sold each year into Cabell County, West Virginia which has a population of 100,000.

**Distributor Claim:** "Distributors must report to DEA each opioid medicine shipped to a pharmacy, hospital, doctor, or other dispenser – not just those we think might be suspicious. Our industry has sent hundreds of thousands of suspicious-order reports to the DEA over the last 10 years."

**Fact:** In 2007 and 2008 drug distributors shipped almost 9 million hydrocodone pills to one pharmacy in the town of Kermit, West Virginia, population 392.

**Distributor Claim:** "A single distributor does not know, and has no way of knowing, if that dispenser has purchased opioids from any other distributor. The DEA has the best information about how many total opioids a pharmacy or doctor is receiving and selling to patients."

**Fact:** In 2007 alone McKesson sent 3,289,900 doses of hydrocodone into Mingo County, West Virginia, whose population in 2007 was 26,679. That was about 124 pills for every man, woman, and child in the county.

**Fact:** McKesson and Cardinal Health shipped 12.3 million doses of powerful prescription opioids to the Family Discount Pharmacy in Mount Gay-Shamrock, West Virginia, from 2006 to 2014. The town in southern West Virginia had 1,779 residents, according to the 2010 Census.

### FOR MCKESSSON, BREAKING THE LAW IS GOOD FOR BUSINESS

In 2007, the government charged McKesson with failing to report suspect opioid orders from some of its customers. In 2008, the company paid a \$13.25 million penalty for its failures and entered into a memorandum of understanding with the government. It promised to develop a controlled-substance monitoring program, or CSMP, and to report any suspicious orders.

Ten years later, the Department of Justice found that McKesson failed to keep its word. In January 2017, McKesson paid a \$150 million penalty and agreed to suspend distribution from some of its centers.

- In total McKesson has paid \$163.25 million for breaking the law and failing to report and halt suspicious opioid orders.
- Opioids now account for about \$4 billion per year in sales for McKesson
- McKesson's CEO and board chairman, John Hammergren, has received \$692 million in compensation for his work since 2008.

According to the 2017 settlement agreement between Department of Justice and McKesson:

- McKesson failed to follow the procedures and policies set forth in the McKesson controlled-substance monitoring program (CSMP) to detect and disclose suspicious orders of controlled substances.
- McKesson failed to report suspicious orders for controlled substances in accordance with the standards identified and outlined by the DEA.
- McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP.
- McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of suspicious orders of controlled substances made by its customers, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. §130 1.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements.
- Certain McKesson Distribution Centers distributed controlled substances to pharmacies even though those Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).

## What do these people have to do with the opioid crisis? They caused it.



# The Data that Opioid Distributors Don't Want Congress to See

DEA ARCOS Reports Are Critical to Holding Opioid Distributors Accountable and Combatting the Worst Drug Epidemic in American History

### What is the ARCOS Database?

- Automated Reports and Consolidated Ordering System (ARCOS) is a data collection in which manufacturers and distributors report their controlled substance transactions to the Drug Enforcement Administration (DEA),
- The ARCOS system monitors the flow of controlled substances from their point of manufacture through commercial distribution channels to the point of sale or

- Why are Drug Distributors Fighting to Keep

  ARCOS Reports Confidential?

  Instead of following through on their duties to monitor and report suspicious shipments of opioids, Wholesale Drug Distributors turned a blind eye as hundreds of millions of opioids flowed into communities across America.
  - O As a result, drug overdoses are now the leading cause of death for Americans under 50, Deand deaths are rising faster than ever and deaths are rising faster than ever.
- The unintentional release of DEA ARCOS data showing the flow of opioids into Weston Nincipia Batterial Bat Virginia between 2007 and 2012 revealed the high level of complicity of wholesale drug# distributors in fueling the opioid crisis.

## West Virginia ARCOS Data Only Scratches the Surface

In December 2016, the Charleston Gazette-Mail obtained previously confidential ARCOS records, which revealed the exact number of pills shipped to and sold to pharmacies in every West Virginia county over a period of six years:

- Between 2007 and 2012, drug wholesalers shipped over 780 million doses of opiate by painkillers to West Virginia, which has a population of 1.8 million.
- Drug distributors supplied West Virginia with roughly 433 pain pills for every man, woman band child in the state.
- In one example, a single pharmacy in a town of just 392 people received 9 million opioid pills in just two years.
- Today, West Virginia has the highest drug overdose mortality rate in the nation, with 41.5 deaths per 100,000.

Congress should demand the release of ARCOS data on the distribution of opioids, nationwide.

Americans have the right to know the extent to which wholesale distributors failed to monitor and report suspicious shipments of opioids and how much they have profited off what is now the worst drug epidemic in history.